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(54) Abstract Title
Cyclically inflatable leg muscle cuff suitable for the prevention of deep vein thrombosis

(57) A calf compression device, suitable for reducing the risks of deep being thrombosis or DVT, comprises an inflatable cuff, which can be wrapped around the whole or part of a leg of a human person, and a pump which is capable of cyclically inflating and deflating the cuff over a regular repeating cycle. Also disclosed is an associated method in which the cuff is placed around a calf, inflated rapidly, such as over 5-10 seconds, to a pressure of between 40-70mm of mercury which is maintained for 10-15 seconds, followed by deflation to ambient pressure over a period of 40-50 seconds. A range of alternative related operating times and pressures are specified. The device may be portable and include a power supply, pressure sensor, timer, and release valve which may all be integral with the device. Alternately, some of the aforementioned components, such as the power supply, power supply and pump, or power supply, pump and timer may be provided in some other fixture such as a bed, car seat or dashboard or aeroplane seat. The invention may further be embodied in two such cuffs and associated components provided in a kit form. Also disclosed is an electric pump and timing device combination providing capable of providing the same timing and pressure conditions as the above mentioned method.

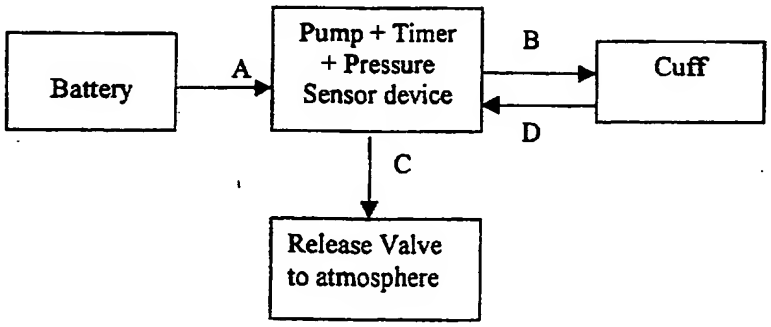

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DIAGRAM 1

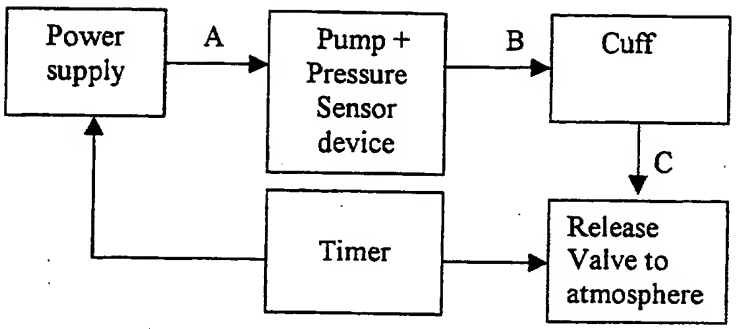
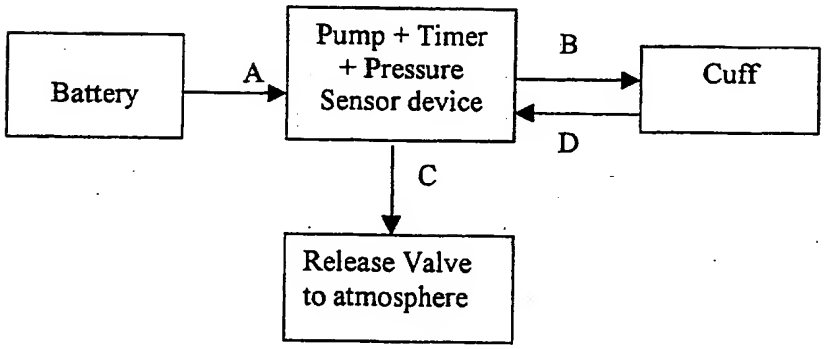


DIAGRAM 2



CALF COMPRESSION DEVICE

This invention relates to calf compression devices and in particular to devices for alleviating deep vein thrombosis.

A significant cause of death is thrombosis, that is the formation of a blood clot or thrombus in a normal blood vessel. The blood clot is probably caused by platelets aggregating at and adhering to the site of an injury in the blood vessel. The aggregation may be reinforced by fibrin and such a thrombus can severely restrict or block the flow of blood in the blood vessel. Whilst such a thrombus may not even be detected in small veins, the blood may entirely clot to form a larger mass. The danger from such a thrombus is that it may become detached and be swept into a vital organ, in particular, the lung where it may cause a disastrous circulatory obstruction. The most commonly occurring thrombotic indications are clots in the leg veins (deep vein thrombosis, sometimes referred to as DVT) and in the lung (pulmonary embolism).

A principal cause of thrombosis is a slowing of blood flow in a number of circumstances. These include confinement to bed or lack of exercise. The problem is exacerbated by other factors such as for example, obesity, malignant disease and blood dyscrasias. DVT may also affect persons of any age, but, in particular, those in older age groups. It may also present a problem in post-operative recovery stages. Of major concern is a period of prolonged inactivity such as during long confinement in an aeroplane, where there is a tendency to sit in cramped conditions relatively inert in an immobile position often for many hours. Furthermore the atmosphere in an aeroplane is often conducive to such inactivity – low cabin pressure, reduced oxygen content and availability of alcohol. This leads to blood pooling in the lower extremities, i.e. in the stem veins of the lower limb. The apparent increase in instances of DVT as a result of air travel (sometimes referred to as "Economy class syndrome") is a major cause of concern, in particular amongst frequent fliers. This has resulted in airlines issuing charts giving details of in flight exercises. However such exercises are often inconvenient because of for instance, interference with cabin staff scheduling, neighbour disturbance.

Whilst DVT may be of most topical concern in relation to air travel, it may also a problem in any situation where there is prolonged restriction of movement. These

situations include long journeys by train and car, persons who have restricted movement due to age and/or ill health, for example, the wheel chair bound.

Thrombosis can be alleviated by medication. Many medicines are available for prescription or hospital use such as for example, warfarin which inhibits clot formation; streptokinase, urokinase, tissue plasminogen activators which dissolve clots; fibrinolytic agents. A commonly used agent is aspirin in low doses. However the use of any of the above medications can be associated with side effects such as bleeding in the digestive tract.

There is therefore a need for a device that can assist in the avoidance of DVT.

Blood pressure is most often measured using a sphygmomanometer. The pressure of blood within an artery is balanced against an external pressure applied to a cuff which is wrapped around an arm. Thus the cuff is wrapped around an arm, the cuff inflated with air from a squeezable bulb and the pressure of air in the cuff is increased sufficient to stop the flow of blood in the artery as heard in an stethoscope placed on the arm below the cuff. Air is gradually released from the cuff through a manually operated valve and the air pressure noted at which blood starts to flow as judged by a soft heart beat (systolic blood pressure); on further releasing the air pressure, that at which the heartbeat disappears is also noted (diastolic blood pressure).

According to the present invention a device for reducing the risk of deep vein thrombosis is provided which comprises an inflatable cuff adapted to be wrapped around the whole or part of a leg of a human person and a pump capable of first inflating the cuff and then deflating the cuff over a regular repeating cycle.

The cuff can be fabricated from any material known in the sphygmomanometer. Generally it will be fabricated from for example from flexible synthetic or natural rubber, or fabric impregnated with a polymeric material to render the material essentially impervious to air, and is preferably shaped to fit the calf. The cuff will be provided with means to retain the cuff in position on the calf. Such means may be for example lacing ties, buckle and strap but are preferably fastening straps made from self fastening material, for example, Velcro ™ and similar materials. Preferably the cuff is reusable, and washable. The cuff will be provided with at least one tube to allow ingress and

egress of air. The cuff may be provided in different sizes so as to accommodate calves of different length and thickness.

In accordance with the present invention the cuff is to be inflated and deflated over a regular repeating cycle. The cycle comprises inflation of the cuff over a period of 1 to 12 seconds to a pressure of between 40 and 70 mm mercury, preferably 50 to 60 mm mercury, maintaining the pressure for 10 to 15 seconds, preferably 11 to 14 seconds, and deflating to ambient pressure over a period of 40 to 50 seconds. Deflation enables complete refilling of the veins. It is important that the inflation step is effected rapidly, that is within 10 seconds of commencement of the cycle, preferably within 5 seconds. Such a complete cycle will generally last for 40 to 90 seconds, preferably 50 to 70 seconds, and is repeated for as long as the pump is activated. By the term "ambient pressure" is generally meant atmospheric pressure, but in some situations, such as in an aeroplane, cabin pressure may be different and hence the term means the local pressure. In this cyclical process, local venous blood flow is improved and normal physiological venous return from the leg or legs is augmented. The risk of developing DVT is thereby reduced.

The cyclical process is facilitated by a pump. The pump supplies gas, generally air, to inflate the cuff, and is preferably battery driven and should be small. The pump can be located, as can its power supply, in the clothing of the person; it may be located on the cuff itself but this likely to be less convenient because of physical interference with movement of the person. If the present devices become generally available, it is envisaged that aircraft seats may provide a plug-in power supply. The pump is conveniently connected to the cuff by flexible tubing fitted with coupling connectors to facilitate connection for use and disconnection when not in use. The pump provides pressurisation of the cuff, and may be provided with a valve to allow slow release of air during deflation. In another embodiment of the present invention, the cuff may be provided with an internal or externally connected valve to release air during the deflation phase, but operation of such a valve should act in phase with the inflation pump so as to provide a cycle hereinbefore described. The cyclical process continues until the power source is turned off, and starts up when the power source is turned on.

Accordingly, the combination of cuff, pump, release valve and power supply is provided with a pressure sensor device and a timer which at the start of the cycle initiates the pump until the required pressure is attained, switches off the pump, holds closed the release valve for a required period, and then opens the release valve so as to release air from the cuff to deflate the cuff at a required rate.

In a further embodiment of the present invention, there is provided an electric, preferably battery-driven, pump and associated timing device adapted to deliver air rapidly to an external closed system to a pressure of between 40 and 70 mm mercury, preferably 50 to 60 mm mercury, to maintain that pressure for 10 to 15 seconds, and then to deflate the external closed system to ambient pressure over a period of 40 to 50 seconds.

Ina further embodiment of the present invention, a method of reducing the risk of DVT is provided which comprises positioning and securing an inflatable cuff around a calf, rapidly inflating the cuff to a pressure of between 40 and 70 mm mercury, maintaining the pressure for 10 to 15 seconds, and deflating to ambient pressure over a period of 40 to 50 seconds.

In a further embodiment of the present invention, a kit or pack of two such devices is provided. In an alternative embodiment, a kit is provided comprising two cuffs and a single pump, so that the pump can pump each cuff in out of phase cycles. Such an embodiment leads to a more efficient use of the power supply which is particularly important where the power supply is battery based.

It will be understood that the pump and/or its power supply might be a fixed facility in an article which accommodates the person wishing to use the device of the invention. Such an article includes for example a wheel chair, a bed, a car, a car seat, an aeroplane seat, and further embodiments of this invention include such articles.

The invention is illustrated with reference to the accompanying figures.

In Diagram 1, the Cuff is inflated by air pumped through flexible tubing B when power is supplied from the Power Supply through cabling A. The pump cuts out when the pressure in the cuff as has reached the required pressure. A pressure sensor device is preferably provided in the cuff or pump to shut off the flow of air from the pump. The

Release Valve is provided with a timer so that after a required period the cuff is deflated through the Release Valve via flexible tubing C. The timer also repeats the cycle after deflation provided that the power supply is still switched on.

In Diagram 2, the Pump and Timer are interconnected in the same unit and provided with an outlet to inflate the cuff through flexible tubing Band inlet for deflating the cuff though flexible tubing D. A pressure sensor device is preferably provided in the pump to shut off the flow of air from the pump. The Pump and Timer unit is provided with a further outlet for controlling Release Valve. In a preferred embodiment, the Battery, Pump, Timer and Release Valve are provided in the same unit, thereby minimising physical size of the device of the invention and providing optimum control of the cycle. Flexible tubing B and D may be co-axial or laterally joined so as to provide single connecting tubing.

In both the embodiments of Diagrams 1 and 2, one or more of the components as appropriate other than the cuff can be provided on the article in or on which the person is accommodated. Hence the Power Supply, Power Supply and Pump, or Power Supply and Pump and Timer may be on or in a bed, car seat, car dashboard or aeroplane seat.

CLAIMS

1. A calf compression device for reducing the risk of deep vein thrombosis which comprises an inflatable cuff adapted to be wrapped around the whole or part of a leg of a human person and a pump capable of first rapidly inflating the cuff and then deflating the cuff over a regular repeating cycle.
2. A device as claimed in claim 1 in which the cuff is rapidly inflated within 5 seconds of commencement of the cycle
3. A device as claimed in either Claim 1 or Claim 2 in which the cycle comprises inflation of the cuff to a pressure of between 40 and 70 mm mercury, maintaining the pressure for 10 to 15 seconds, and deflating to ambient pressure over a period of 40 to 50 seconds.
4. A device as claimed in any one of Claim 1 to 3 in which the cuff is inflated to a pressure of between 50 and 60 mm mercury.
5. A device as claimed in any one of Claim 1 to 4 in which the cuff is maintained at the inflated pressure for between 11 to 14 seconds.
6. A device as claimed in any one of Claim 1 to 5 in which the cycle lasts for 50 to 70 seconds.
7. An electric pump and associated timing device adapted to deliver air rapidly to an external closed system to a pressure of between 40 and 70 mm mercury, to maintain that pressure for 10 to 15 seconds, and then to deflate the external closed system to ambient pressure over a period of 40 to 50 seconds.
8. A method of reducing the risk of DVT which comprises positioning an inflatable cuff around a calf, rapidly inflating the cuff to a pressure of between 40 and 70 mm mercury, maintaining the pressure for 10 to 15 seconds, and deflating to ambient pressure over a period of 40 to 50 seconds.

9. An article for accommodating a person wishing to use the device as claimed in any one of claims 1 to 6 which includes a dedicated power supply, power supply and pump, or power supply and pump and timer.

10. A kit which comprises a pair of devices as claimed in any one of claims 1 to 6

Application No: GB 0129554.2
Claims searched: 1-6, 8-10

Examiner: Michael Young
Date of search: 19 June 2002

Patents Act 1977
Search Report under Section 17

Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.T): A5R (RBP)

Int Cl (Ed.7): A61F 5/01, 5/34, A61H 23/04

Other: ONLINE: WPI, EPODOC, JAPIO

Documents considered to be relevant:

Category	Identity of document and relevant passage		Relevant to claims
X	GB 1599607	(WHITNEY) whole document relevant	1,2,9,10
X	GB 1426439	(BOC) whole document relevant	1,2,9,10
X	EP 0392670 A2	(KENDALL) whole document relevant	1,2,9,10
X	WO 99/37266 A1	(IBRAHIM) whole document relevant	1,2,9,10
X	US 6296617 B1	(PEELER) whole document relevant	1-6,8-10
X	US 6290662 B1	(MORRIS) whole document relevant	1,2,9,10

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Y Document indicating lack of inventive step if combined with one or more other documents of same category.
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